K072237

5 510(k) Summary

OCT 10 2007

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I. General Information

Establishment	Siemens Medical Solutions. Inc. 51 Valley Stream Parkway Malvern. PA 19355
Registration Number	2240869
Manufacturer	Siemens AG. Bereich Med Henkestrasse 127 D-91052 Erlangen. Germany
Registration Number	8010024
Contact Person	Ms. Judy Campbell Technical Specialist. Regulatory Submissions 51 Valley Stream Parkway Malvern. PA 19355 Phone: (610) 448-4918 Fax: (610) 448-1787
Device Name	Trade Name: MAGNETOM Verio

Classification Name:	Magnetic Resonance Diagnostic Device
CFR Code:	21 CFR § 892.1000
Classification:	Class II

Performance Standards
None established under Section 514 the Food. Drug. and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

Intended Use

The MAGNETOM Verio is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Depending on the region of interest, contrast agents may be used. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM Verio may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in room display and MR-safe biopsy needles.

Device Description

The MAGNETOM Verio comes with I-class and T-class releases based on *syngo* MR B15B. It is a 3 Tesla MR scanner based on a superconducting magnet. It consists of the same types of hardware (with a modified magnet, gradient coil and RF body coil) that are currently available with the MAGNETOM Trio a Tim system including Matrix Coils and Total Imaging Matrix (Tim) technology.

Substantial Equivalence

The system is substantially equivalent to the following cleared medical devices:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens 3T MAGNETOM Trio a Tim System	K050200	Feb 28, 2005
software *syngo* MR B15 (VB15A)	K062454	Nov 3, 2006

General Safety and Effectiveness Concerns:
Operation of the MAGNETOM Verio is substantially equivalent to the commercially available MAGNETOM 3 T Trio a Tim System.

As specified in the FDA guidance document "Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Devices" the following measurements of performance and safety data have been performed following National Electrical Manufacturing Association (NEMA) or equivalent IEC and ISO standards.

Safety
Static Field Strength
Acoustic Noise
dB/dt
RF Heating
Biocompatibility

Performance
Signal-to-Noise Ratio
Geometric Distortion
Image Uniformity
Slice Thickness
Spatial Resolution

The MAGNETOM Verio will conform to the measurement of safety parameters to the international IEC, ISO and NEMA standards for safety issues with Magnetic Resonance Imaging Diagnostic Devices.

Furthermore performance measurements have been done on MAGNETOM Verio and MAGNETOM Trio a Tim System to show that the performance of the MAGNETOM Verio is equivalent with respect to the predicate device MAGNETOM Trio a Tim System.

This will assure that the performance of MAGNETOM Verio is substantially equivalent with respect to the currently available MAGNETOM Trio a Tim System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2007

Ms. Judy Campbell
Regulatory Technical Specialist
Siemens Medical Solutions USA, Inc.
Corporate Headquarters
51 Valley Stream Parkway
MALVERN PA 19355

Re: K072237
Trade/Device Name: MAGNETOM Verio
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: August 8, 2007
Received: August 13, 2007

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1796, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known) K072237

Device Name: **MAGNETOM Verio**

Indications for Use:

The MAGNETOM Verio is indicated for use as a magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that displays the internal structure and/or function of the head, body, or extremities. Depending on the region of interest, contrast agents may be used. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

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(please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use____ OR Over-The-Counter Use____

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K072237